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EXAMINER	
FORD, JOHN K	
ART UNIT	**PAPER NUMBER**
3753	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/057,610	Wisniewski et al.
	Examiner	Art Unit
	FORD	3753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10-9-03 + 4-21-03

2a)☑ This action is FINAL. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) 6-19 is/are withdrawn from consideration.

5)☐ Claim(s) ____ is/are allowed.

6)☑ Claim(s) 1-5, 20-29 is/are rejected.

7)☐ Claim(s) ____ is/are objected to.

8)☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on ____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on ____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. ____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☑ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ .

18)☐ Interview Summary (PTO-413) Paper No(s). ____ .

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Applicant's first and second declarations have been received, with the October 9, 2003 response. In addition, applicant and counsel have stated for the record that they will not contact Genentech (Mr. Wisniewski's former employer) to obtain additional information about the prior art 1992 biopharmaceutical freezer that Mr. Wisniewski (and, apparently, Mr. Wu) developed during his employment at Genentech. In refusing the Examiner's request to obtain the relevant dimensions of this prior art device, counsel states that it is "unnecessary and goes beyond the duty owed to the Patent Office by an inventor or their representatives." The Examiner will not make any further inquiry in light of this refusal, as apparently it would be fruitless. The tiresome inquiry has thus far yielded a few additional details from Mr. Wisniewski (e.g. the 1992 article and the 1996 Advanstar Reprint which were not originally submitted to the PTO, only the 1996 DMT article was, and the second declaration paragraph 8 admission that "I know that this distance was greater than 4 inches"), but has largely exceeded in wasted examination time what was extracted in terms of additional details about the prior art, with the exception of the 1992 article and the 1996 Advanstar equivalent.

<u>First declaration</u>

Paragraphs 1 – 4, no dispute.

Paragraph 5, the 1992 and its equivalent 1996 Advanstar publications were not disclosed to the PTO originally. Only a 1996 DMT article was disclosed which contains

very few details of the prior art Genentech device. Only through the Examiner's inquiring was the 1992 article and its 1996 Advanstar equivalent made of record.

Paragraph 6, Mr. Wisniewski admits that he designed the internal heat transfer coil with fins for the Genentech device, the details of which he does not, now, recall. While the 1992 article does not explicitly discuss a "thermal bridge" there is nothing, which suggests one did not form. The absence of any specific discussion is not necessarily evidence that the phenomena did not take place. It is respectfully submitted that a thermal bridge would inherently form in the 1992 Genetic device because the vessel wall during the chilling process will always be at a lower temperature that the central structure because the coldest coolant is directed to the jacket first and then the (now slightly warmed coolant) is directed to the central structure by virtue of the piping system clearly disclosed in the 1992 article.

Paragraph 7. Mr. Wisniewski's projections are no more than <u>guesses</u> of what the temperature distribution would be. It is respectfully submitted that these freezing phenomena are so complex that no human being including one with nearly 30 years of experience can accurately predict such results. Purporting to have such ability only diminishes ones credibility. One need not look far to see that the Examiner is correct. The Kalhori and Ramadhyani (K & R) article which involves solid phase change around a structure somewhat simpler than the 1992 Genetic device states:

"As will shortly become evident, the problem of phase change around an embedded vertical cylinder is a moving boundary problem in a complex geometry. An analysis of the problem would involve the solution of the energy equation coupled with hydrodynamic equations in the liquid phase. This is a challenging task that is amenable ***only*** to a numerical solution. Consequently, in addition to providing information of utility in the design of thermal storage units, data from the present study could be useful in validating a numerical solution of the problem." (emphasis supplied).

Thus, researchers, other than Mr. Wisniewski, state that accurate modeling of phase change heat transfer in tanks with finned element such as shown in Figure 3 of the K & R article can only be done by computers or by direct empirical measurement.

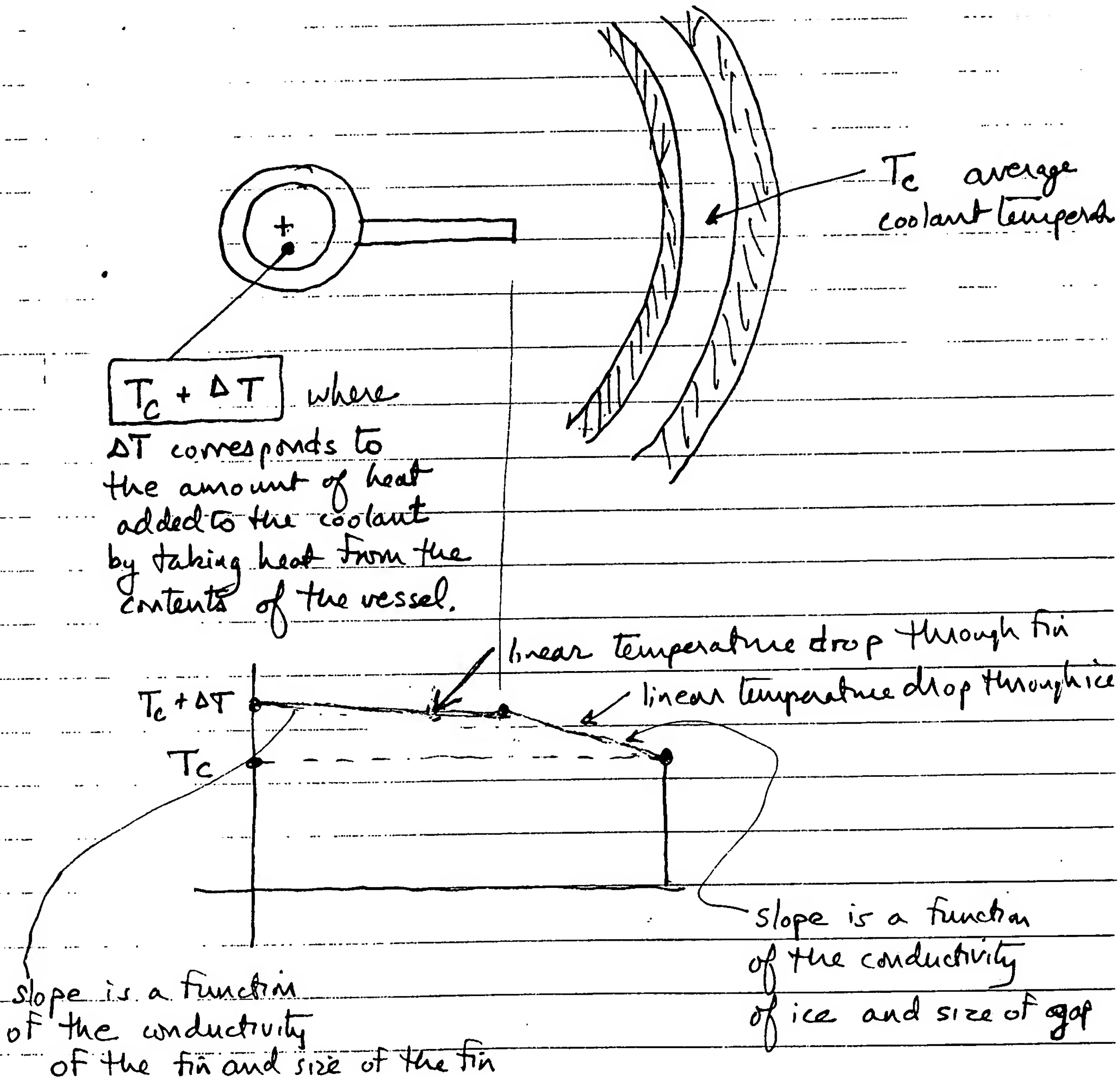
For this reason the Examiner does not find Mr. Wisniewski's thought experiments as credible evidence of what the actual temperatures are in the 1992 Genentech device. The Examiner has repeatedly asked Mr. Wisniewski to test this prior art, or a reasonable facsimile of it, using temperature transducers and Mr. Wisnieski has refused thus far.

Moreover, Exhibit B incorrectly assumes the temperature in the pipe is the same as the temperature in the jacket. This is an incorrect assumption and will necessarily lead to inaccurate conclusions. The temperature in the pipe is a complex function of the initial temperature of the coolant before it passes through the jacket, the temperature of

the liquid in the container and the flow rate of the coolant among other variables. As explained above, and as shown in Figure 1 (page 134) of the 1992 article, the coolant goes from the refrigeration system to the jacket and only after exchanging heat with the contents of the vessel (and thereby acquiring some higher temperature) does it pass into the central structure where it necessarily must have a higher temperature than the coolant in the jacket. Thus, Mr. Wisniewski's thought experiments are flawed because they are based on incorrect boundary conditions.

Paragraph 8, Exhibit C, like Exhibit B is simply a guess at what the temperature distribution actually is. As stated with respect to Exhibit B, the temperature distribution must either be measured or generated by very sophisticated computer programs, which have had their validity checked against measured data. Mr. Wisniewski has not done this. The results are not credible, for this reason.

Paragraph 9, Exhibit D is clearly erroneous, beyond the reasons stated above. Once the ice bridges the entire gap to a significant extent, the temperature distribution through a solid ice (non-moving interface) is relatively easy to predict analytically and Mr. Wisniewski's analysis can be shown to be incorrect. The correct analysis to a first approximation, which can be done by anyone of ordinary skill in the art, is given below:


T_c average coolant temperature
$T_c + \Delta T$ where
ΔT corresponds to the amount of heat added to the coolant by taking heat from the contents of the vessel.
linear temperature drop through fin
linear temperature drop through ice
$T_c + \Delta T$
T_c
slope is a function of the conductivity of ice and size of gap
slope is a function of the conductivity of the fin and size of the fin

Paragraph 10, these allegations are not supported by valid factual materials. Mr. Wisniewski's guesswork even in declarative form are simply no substitute for real evidence. Neither he nor any other person on the planet is in a position to properly guess at the actual temperature distribution. The analysis in paragraph 10, is true no matter how large the gap is. Initially heat will be transferred from the fluid in the gap to both the fin and and the wall, regardless of gap size. This process will persist longer in a large gap than a small gap but the physics of the problem is the same regardless of gap size. Applicant is free to rebut this analysis with real evidence (i.e. test results) not idle speculation.

Second Declaration

Paragraphs 1 – 4, no dispute.

Paragraph 5, Mr. Wisniewski did not disclose the 1992 article or its 1996 equivalent until the Examiner required its disclosure. Moreover Mr. Wisniewski continues to co-write articles with Mr. Wu including an article written in 2000 entitled "Scale – Down Approach to Large Volume Cryopreservation of Biopharmacenticals Using the Cryo Cassette and CryoWedge." Mr. Wisniewski has not contacted Mr. Wu to see what he remembers about the Genentech device inspite of repeated requests by the Examiner for additional information.

Paragraph 6, appears to refer to an office action in another application, not that mailed February 11, 2003. It is on this basis disregarded.

Paragraphs 7 and 8, for the reasons stated previously, it defies imagination that Mr. Wisniewski could remember the tip to wall distance as greater than 4 inches yet recollect nothing else about the prior art including the approximate size of the vessel (i.e. whether or not he could get his arms around it or pick it up etc.). It is also not understood why he doesn't contact Mr. Wu with whom he co-wrote an article as recently as the year 2000 to see what he remembers of the Genentech device, nor is understood why Genentech would not cooperate given that Genentech is a <u>customer</u> of Integrated Biosystems according to John H. Brown the president and CEO of Integrated Bio Systems. Counsel has gone on the record (Paper No. 8, page 2) stating that Genentech is a <u>competitor</u> of Integrated Bio system, an allegation, offered as fact, that does not appear to comport with reality. The remainder of the factual allegations in paragraph 8, which reiterate those made in the first declaration, are not credible for the reasons enumerated in the Examiner's critique of the first declaration.

Finally, as demonstrated by the article in BioPharm, Vol. 15, No. 5, May 2002, Mr. Wisniewski and his assignee have very sophisticated software and hardware at their disposal to perform the testing that the Examiner believes is required to establish the truth of the matter asserted. On page 4 of that article a CryoWedge 20 is disclosed

which appears to be used to do the sophisticated type of testing that has been studiously avoided in these applications. If Mr. Wisniewski's hand drawn sketches were accurate it is submitted that Integrated Biosystems would have no need for the Cryowedge 20 or any of the other sophisticated models and programs discussed in that article. It is also noted that Genentech is disclosed to be a customer of Integrated Biosystems not a competiter as alleged by counsel in his latest remarks (Paper No. 8, page 2, paragraph 2, line 6) calling the Genentech prior art "a competive system" Note John Brown in the Wall Street Journal interview called Genentech a customer of Integrated Biosystems. Each of these units according to Mr. Brown can cost upwards of $ 40,000 - $100,000. With those kinds of numbers and the sophisticated modeling and equipment to perform experiments that exist at Integrated Biosystems the Examiner is completely perplexed with Mr. Wisniewski's and counsel's representations that the PTO has to accept Mr. Wisniewski's hand drawn sketches based on speculative guesswork involving dubious assumptions as the best evidence applicants' possess. Clearly applicants are in a position to present much more legltimate evidence of actual temperature profiles in both their own device and in the prior art than what they have disclosed here.

Given all of the other information that has been given which is incorrect the Examiner does not see how it is possible for Mr. Wisniewski to remember that the fin tip to wall distance was greater than 4 inches yet fail to recall <u>any</u> other relevant dimension of the prior art (with the same degree of imprecision) including the overall size of the

tank. It does not seem plausible to the Examiner. Paragraph 8 is contradicted by the 1992 article where it is explicitly states that the fins were there to form compartments. Mr. Wisniewski's statements that they were only there to increase heat transfer contradict the 1992 article and are not credible. The conclusion, unsupported by any facts, that no thermal bridge was formed in the 1992 Genentech device is similarly not credible.

In paragraph 9, Mr. Wisniewski has simply refused to provide a sketch of the admitted prior art in the parent applications as required in Paper No. 5, page 3, lines 3 – 14. Instead USP 2,441,376 and USP 2,129,572 (references that Mr. Wisniewski was not even aware of at the time that the parent applications were written) are offered instead. Please comply with the sketch requirement. These two references do not correspond to what is disclosed to be the prior art in col. 1, line 33 – 47 of USP 6,196,296, counsel's and applicant's statements to the contrary notwithstanding. The Examiner did not ask about the prior art where the fin was attached to both walls. The Examiner asked for a specific sketch and it has not been produced.

Finally, in paragraph 10, Mr. Wisniewski simply states a conclusion without any legitimate testing to support it. Once the medium is frozen in the gap, the Genentech device will have a "thermal bridge" formed given how that term is defined in the current specification and that of the parent applications.

Claims 1-5 and 20-29 are rejected under 35 U.S.C. 112, second paragraph, as set forth in this Office action, below:

The term "biopharmaceutical product"as it is used in this application is ambiguous and hence its use in claims 1, 20 and 25 is also the source of ambiguity. In contrast with what may be accepted 'biopharmaceutical products" such as a product derived from biological sources that has an intended therapeutic application and whose manufacturing is or will be regulated by pharmaceutical or veterinary regulatory agencies (see '132 declarations in Paper No. 4 of SN 09/443,838), in the specification applicants state that the present invention can be used "freeze and preserve a variety of biopharmaceutical products, including but not limited to proteins, cells antibodies, medicines, plasma, blood, buffer solutions, viruses, serum, cell fragments, cellular components, and any other biopharmaceutical product."

Many of the purported biopharmaceuticals on applicants' list in the specification are not normally considered biopharmaceutical products by applicants' definition (offered up in the '132 declarations in Paper No. 4 of SN 09/443,838) above. For example, buffer solutions are acids or bases-dissolved in water not derived from biological sources nor regulated by FDA to the Examiner's knowledge. Blood, per se, such as is drawn from the general population by the Red Cross would not appear to be a biopharmaceutical by affiants' definition yet it appear on applicants' list. On page 133, col. 1, fourth full paragraph, of the 1992 Wisnewski and Wu prior art it states that "buffer

salts" can be <u>components</u> of a biopharmaceutical product. "Medicines" are simply understood to be drugs or other agents used to treat disease or injury. They need not be derived from biological sources. What is vital to this examination is to know with reasonable particularity what chemicals when placed in applicants' tank would infringe the claims. Under applicant's expansive definition of biopharmaceuticals in the specification it would appear that many conventional organic and inorganic solutions (e.g. buffer solution) would be included – against what affiants Arathoon, Burman, Lawlis and Vetterlein (Paper No. 4 of SN 09/443,838) would consider to be the reasonable limits of the word. On the other hand, orange juice, recently shown to have measurable effects against many forms of cancer, was suggested by counsel to not seriously be considered a biopharmaceutical. The Examiner disagrees. If buffer solutions are considered to be biopharmaceuticals and blood, per se, drawn from the general population is a biopharmaceutical, it doesn't seem reasonable to exclude orange juice. The chances of the FDA regulating "buffer solutions" as a biopharmaceutical in the future would be about on par with the chances of the FDA regulating orange juice as a biopharmaceutical in the Examiner's opinion. If the definition now includes orange juice based on new research showing its anticancer properties and possible further regulation by the FDA then applicants' use of the word biopharmaceutical seems to include an ever growing and somewhat amorphous list of chemicals that would be perpetually changing as new research was done to show therapeutic properties to products produced by biological processes such as photosynthesis, fermentation and biological agents such as herbs, roots and

compounds which are essentially the products of nature. It is impossible to know which of these the FDA will regulate in the future given the vicissitudes of government regulation. The term "biopharmaceutical product" as it is used in the originally filed application is deemed by the Examiner to be one that violates the tenets of 35 U.S.C. 112, second paragraph, in that the metes and bounds of the claims cannot be established with the requisite clarity required by the statute and are subject to change based on future (unpredictable) FDA actions. The would-be-infringer would have no clear way of determining infringing behavior, to put it another way. Infringement would be constantly changing depending on what the FDA decided to regulate as a biopharmaceutical. It is noted that the FDA regulates the handing and composition many food items, but that doesn't transform them into biopharmaceuticals even if those food items have some therapeutic benefit. The definition offer by the declarants appears to be unworkable in the Examiner's opinion and that offered in the specification ambiguous.

The declarations under Rule '132 by Arathoon, Burman, Lawlis and Vetterlein (see Paper No. 4 of SN 09/443,838) all appear to define "biopharmaceutical products" much more narrowly than the expansive definition given in the specification and in the 1992 article by Wisniewski and Wu. For example, the Examiner knows of no biologically sources "buffer solution" which in and of itself is regulated by the FDA. Moreover, if there were such a solution, why would it freeze any differently than a buffer solution not regulated by the FDA nor biologically sourced? It is noted that there is a

tremendous variety of "biopharmaceutical products" in applicants' list some of which are very large: cells (e.g. blood etc) whereas others are millions if not billions of times smaller (e.g. viruses or salt ions in a buffer solution). It is submitted that the freezing characteristics of solutions at these two extremes would be extremely different. Blood would probably freeze more in the manner of orange juice or milk given its nearly macroscopic cellular nature whereas virus in a suitable buffer solution or water would freeze in the manner of pure or salty water. Moreover Applicants' response (pre-final amendment in SN 09/443,838) as well as the declarations under Rule '132 have failed to reconcile the definition of "biopharmaceutical products" stated in the declarations with the disclosure of the chemicals and blood products, medicines, buffers etc. offered up as examples of "biopharmaceutical products" in the specification. The specification definition of biopharmaceutical products clearly encompasses more chemicals than Affiants' declarations under Rule '132. To the extent that the Rule'132 declarations define the term "biopharmaceutical product" more narrowly that what is discussed in the specification, the declarations serve to heighten the ambiguity of the disclosed and claimed 'biopharmaceutical products" and what the limits (metes and bounds) of that terminology is to have as a claim limitation. Moreover, in regard to the cited prior art, nothing in the declarations has addressed why one designing freezing equipment for the chemicals disclosed in the specification would <u>not</u> look to the art of freezing water, orange, juice or solids suspended in liquids.

The following is a quotation of 35 U.S.C. 103 (a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5 and 20-29 are rejected under 35 U.S.C. 103 (a) as being unpatentable over the combined teachings of the 1992 publication by Wisniewski and Wu and the 1986 Kalhori and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder with or without fins, embedded in a solid phase change medium" (reference 29 on page 140 of the 1992 article by Wisniewski and Wu) and West USP 2,114,642.

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange member (i.e. fins) in close spaced proximity to the interior surface of the container. It lacks a "spur tube" type cooler in the center. See Figure 1 and the description thereof found on pages 134 and 136. Note

page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is no explicit disclosure of any thermal ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer bridge", however see specification, paragraph 0020, for apparently inconsistent definition: when the medium is being heated, after being frozen, the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in the "gap", hence it would appear that "thermal transfer bridge" is much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they must extend far enough to define "compartments" between the fins (1992 Wisniewski and Wu research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaced cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP 983,466, page 1, col. 2, line 97 – page 2, col. 1, line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131-01, sub-section III), wherein it states:

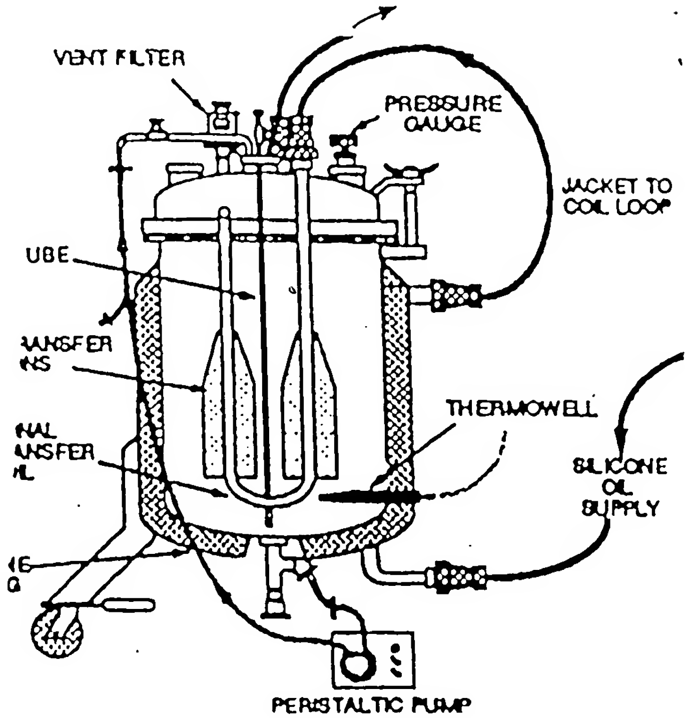
"Whether ice forms in single cakes about several freezing elements or forms in a single cake enclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be ***close together*** the ice surrounding these element will ***coalesce into a single cake***; and after this has occurred freezing will go on from the surface of the combination cake so formed..."

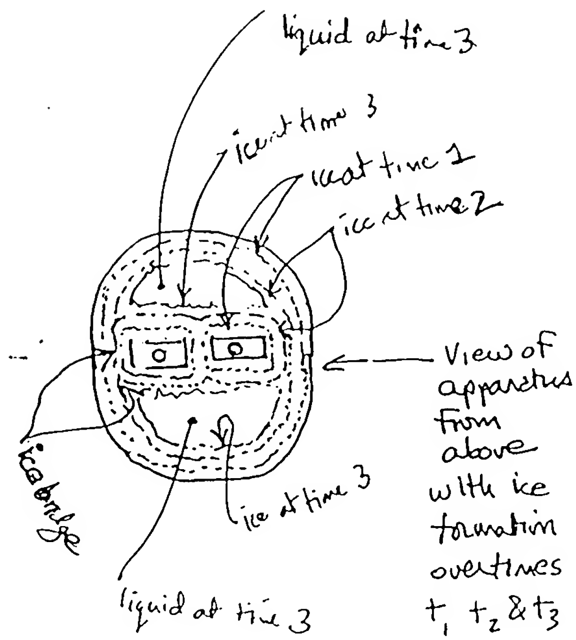
(Emphasis supplied).

Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

"I have shown a number of other elements so spaced relatively as to form a single cake 15 of length comparable to cakes formed in plate processes. Of course if the ***freez-ing were continued indefinitely the cakes 12,13, 14 and 15 would eventually coalesce and freeze to the sides of the tank..."***

It is evident that ice will build upon the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3,318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly cooled surface and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchange fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process progresses over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on the next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.





Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins "in close spaced proximity" to the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point "in close spaced proximity" to the interior surface to the container in order to advantageously increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects" (1992

publication, page 136, col. 1, first full paragraph) would have been obvious to one or ordinary skill in the art.

The examiner submits that the fins shown in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would only be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain **efficient heat transfer** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: " The heat transfer fins were configured to **divide the tank into compartments** to decrease the freezing and thawing time and to reduce cryoconcentration effects. **Compartmentation** of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration." (Emphasis supplied). The fins are designed to maintain "efficient

heat transfer during freezing and thawing" (page 134, col. 2, 1992 Wisniewski and Wu publication). Figure 1, page 134, of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly for the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification.

West (USP 2,114,642) teaches in Figures 3, 5 and 6 a central spur-tube heat exchanger used in combination with an external cooler (shown in Figure 6) to cool product as shown in Figure 5. Such a cooler advantageously reduces cryoconcentration as discussed on page 2, col. 1, line 73 – page 2, col. 2, line 33, incorporated here by reference. As shown in Figure 5, the fins 15 extend radially outward to a point close to the container 8 and thereby "compartmentalize" the to be frozen substances.

The 1986 Kalhori and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in solid phase change medium" (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), like applicants have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current application. The finned heat exchanger as shown is immersed in a container of paraffin and the melting and freezing

processes were studied in great detail with a material, paraffin, of known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins in improving heat exchange. See last sentence of article-"In view of the ***superior heat transfer characteristics, the finned cylinder*** is a much better choice of the design of a practical thermal storage unit." (Emphasis supplied).

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136).

Extending the fins to substantially the inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area,
b. Improve "compartmentation" by forming ice bridges and
c. Reduce cryoconcentration.

To have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 improve heat transfer and to facilitate

ease of construction as well as to facilitate easy removal from the frozen mass would have been obvious to one of ordinary skill in the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication should be directed to John Ford at telephone number 703-308-2636.

John K. Ford
Primary Examiner